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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,832	07/01/2003	Harald Stein	086035-000000US	3864

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,832	STEIN ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14,18,19,21,22 and 24-33* is/are pending in the application.

4a) Of the above claim(s) *8,10,12-14,19,21,22,24-28 and 31-33* is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☒ Claim(s) *7,9,11,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Argument and Amendment

The Amendment filed on 2/27/2007 in response to the previous Non-Final Office Action to RCE (11/17/2006) is acknowledged and has been entered.

Claims 1-6, 15-17, 20, 23 are cancelled. Claims 31-33 are added. Claims 7-14, 18, 19, 21, 22, and 24-33 are pending. Claims 8, 10, 12-14 and 19, 21, 22, 24-28 have been withdrawn for non-elected invention previously. Newly added claims 31-33 depending on the withdrawn claim 19 are also withdrawn from consideration currently. Thus, claims 7, 9, 11, 18, 29 and 30 are under the consideration.

The following office action contains NEW GROUNDS of rejection.

Rejections/Objections Withdrawn

1. Claim objections (objections 2, 3, and 4) are withdrawn in view of the amendments to or cancellation of the claims.

2. Rejection of claims 1, 6, 7, 9, 11, 15-18 and 29-30 under 35 U.S.C. 112, second paragraph is withdrawn in view of cancellation of base claim 1.

3. Rejection of claims 1, 6, 7, 9, 11, 15-18 and 29-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of cancellation of and amended to the claims.

4. Rejeciton of claims 1, 6, 15-17, and 29-30 under 35 U.S.C. 102(b) as being anticipated by Lemke et al., is withdrawn in view of cancellation of and amendment to the claims. However, the amended claims are still anticipted by Lemke et al., (see new group rejection below).

5. Rejections of claims 1, 6, 15-17, and 29-30 under 35 U.S.C. 102(e) as being anticipated by Mohler et al., is withdrawn in view of cancellation of and amendment to the claims.

6. Rejection of claims 9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Mohler et al., applied in the claim 1 above and further in view of Deonarain et al., is withdrawn in view of cancellation of claim 1, however, the claims are unpatentable over Lemke et al., in view of Deonarain et al., (see new group rejection below).

Response to Arguments

Sequence Requirements

SEQ ID No(s) remain required for the sequences in specification on pages 12 and 15 and amended specification on page 16.

Applicant stats amendment made on June 15, 2004 to insert the sequence SEQ ID NO: 1-12 on page 12 and 15 of the specification. In response to this argument, the Office carefully review the file history and note that applicant amended specification on Sep 09 2005, in which page 16 contain the sequence, which have no SEQ ID NOs associated. Thus, applicant needs to comply with the sequence rules to add SEQ ID NOs to those sequences and to check the entire disclosure and file history to ensure that the application is in sequence compliance.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attached form, PTO L90).

Claim Objections

The claim 9 remain objected to as failing to provide proper antecedent basis for the claimed subject matter as the following because Applicant does not response to this objection or amend claim 9 based on the objection.

Claim 9 is dependent on claim 8, which is drawn to a non-elected invention (toxin). Morever, claim 8 is only drawn to a toxin, claim 9 is drawn to toxic proteins, enzymes, or proenzymes, claim 9 does not further limit the claim 8. For the purpose of examination, claim 9 is treated as further drawn to claim 1.

The following is a New Ground of rejection-based on the amendment to the claims

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemke et al., (US Patent NO: 6033876, Mar, 2000, provide in previous office action).

Amended claim 7 is drawn to a reagent that binds CD30 wherein the reagent is a humanized version of the antibody that binds CD30 at the same epitope as the antibody produced by the cell DSZ1 (claim 7(3)). Claims 29-30 are drawn to a composition or a CD30 diagnosing kit comprising the reagent of claim 7. For this rejection the intended use of a composition and diagnostic agent is given no patentable weight.

Lemke et al., disclose anti-CD30 antibody, Ber-H2, binding to CD30 epitope. Lemke et al., disclose that the antibody can be used as whole monoclonal antibodies and humanized antibody for treating a disease (col 4, line 52-60, and col 6). Ber-H2 antibody disclosed by Lemke et al., binds to the same epitope of CD30 shown as amino acid sequence DCRKQCEPDYYLD and GDCRKQCEPDYYL (see specification page 15) as evidenced by Dong et al., (figure 1, J of Molecular Recognition, vol 16 page 28-36, 2003). Lemke et al., also disclose a composition comprising the antibody to CD30 (col 6, line 20-30), which is used for inhibiting release of soluble CD30 (col 2 and col 9-10).

Although Lemke et al., do not explicitly teach a kit containing the antibody for diagnosing or treating CD30 related disease, claim 30 is anticipated by Lemke et al., because Lemke et al., disclose diagnosis of a disease with the antibodies to CD30, because formation of a kit using known component is within the purviews of one skilled in the art and because claim 30 recites a kit comprising antibody to CD30 for diagnosing a disease and a instruction of using the reagent. See MPEP 2112.01-III as following:

> Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, ___ F.3d ___, 2004 WL 1068957 (Fed. Cir. May 13, 2004.

Response to applicant's argument.

Applicant argues the rejection (Lemke et al., page 11) and states in view of the present amendment "the structural feature of the CD30-binding reagent in its CD30-binding domain are the same as the antibody produced by the DSMACC2548 cell or contain only specifically defined modification" and states "amended claims is free of art". In responses to this argument, claim 7 as amended, is drawn to an antibody to CD30 that binds to the same epitope as the antibody produced by cell DSZ1. As stated in the rejection above, Lemke et al. disclose antiCD30 antibody, Ber-H2, that binds to the same epitope as the antibody produced by cell DSZ1. Thus, Applicant's argument has not been found persuasive, and the rejection is made for reason of the record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al., and evidenced by Dong et al., applied in the claim 7 above and further in view of Deonarain et al., (Br J Cancer, vol 70 page 786-94, 1994, provided in previous office action).

Claims 9 and 11 are further drawn to claim 7 (see objection), wherein the reagent is linked with enzymes from the group of the phosphodiesterases.

Lemke et al., teach humanized anti-CD30 epitope antibody, Ber-H2.

Lemke et al., do not teach that the antibody is linked to an enzymes or phosphodiesterases.

Deonarain et al., teach ribonuclease (RNas), an enzyme from group of phosphodiesterases, and using the enzyme for cancer therapy. Deonarain et al., also teach that RNase is fused to an antibody or an antibody fragment. Deonarain et al., further teach that the fusion protein is cytotoxic to the cells at low concentrations (page 792, column 1, paragraph 1).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teaching of Deonarain et al., with the teaching of Lemke et al., in order to benefit the conjugated antibody for treating a disease associated with CD30 antigen expression comprising cancer because Deonarain et al., teach that RNase fused to an antibody is used for the cancer therapy. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to make the conjugated antibody linked to a phosphodiesterases by combining the teaching of Deonarain et al., with the teaching of Lemke et al., because Deonarain et al., have shown the enzyme and a method of making the conjugate antibody comprising the enzyme and Lemke et al., have shown the Ber-H2, binding to the same epitope of CD30 as antibody produced by cell DSZ1 evidenced by Dong et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Response to applicant's argument.

Applicant argues the rejection (Lemke et al., in view of Deonarain, page 11) for the same reason, which has been discussed above. Thus, Applicant's argument has not been found persuasive, and the rejection is made for reason of the record.

Conclusion

Claim 18 is allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

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